REMARKS/ARGUMENTS

Claims 1, 2, 4, 6 and 8 are pending in the instant application. Claims 11 through 15 have been withdrawn from further consideration pursuant to 37 CFR §1.142(b). Claims 3, 5, 7, 9 and 10 are also withdrawn from further consideration as being drawn to a nonelected species. Claim 2 has been amended to correct a discovered informality.

The present amendment corrects a discovered informality in claim 2 without the introduction of new matter, and is submitted in accordance with the provisions of 37 C.F.R. §1.116, which after Final Rejection permits entry of amendments placing the claims in better form for consideration on appeal. As the present amendment merely corrects a discovered informality in claim 2 and as the present response is believed to overcome outstanding rejections under 35 U.S.C. §§ 102 and 103, without raising any new issues requiring the Examiner's further search and/or consideration, the present amendment places the application in better form for consideration on appeal. It is therefore respectfully requested that 37 C.F.R. §1.116 be liberally construed, and that the present amendment be entered.

The Examiner has rejected (i) claims 1, 4 and 6 under 35 U.S.C. §102(b) as being anticipated by Burton, U.S. Patent No. 4,159,720, and (ii) claim 2 under 35 U.S.C. §103(a) as being unpatentable over Burton in view of Davis et al. U.S. Patent No. 3,474,703. The Examiner is of the view that (emphasis added):

> With regard to claim 1, Burton discloses a braided suture having proximal and distal ends (see entire document). As shown in Figure 14, the suture comprises a hollow inner passageway coaxial with the braided suture (column 4, lines 46-49). A prescribed fluid runs through this passageway to facilitate healing of the damaged tissue (column 2, lines 13-18). The hollow inner passageway comprises holes (102) that connect the inner passageway to the outer surface of the suture tube (column 4, lines 46-49; Figure 14). Each hole (102) comprises an outer

opening along the outer surface of the suture and an aperture that connects to the outer opening and penetrates into the hollow inner passageway. Therefore, it is the examiner's position that the each outer opening of 102 overlaps the instantly claimed interstices and the each aperture of 102 overlaps the instantly claimed openings. However, Burton does not specifically disclose wherein the distal end of the passageway is disposed between the proximal and distal ends of the braided suture. If this were not the case, then the distal end of the passageway would be open, allowing the fluid to directly flow into the passageway. However, Burton teaches that the ends of the suture absorb the fluid (column 5, lines 6-8). Therefore, **since the fluid is absorbed, suture material must be present at the distal end to take in the fluid**.

With regard to claim 4, it is the examiner's position that the inner passageway is a lumen of a tube.

With regard to claim 6, the apertures of 102 overlap the instantly claimed holes that connect the lumen (inner passageway) to the outer surface of the tube (outer surface of suture).

Burton, as disclosed in paragraph 2 above and incorporated here by reference, discloses a suture comprising an inner lumen and a plurality of interstices along the outer surface. Burton further discloses wherein the suture is a wick and utilizes capillary action to move liquid along its length (Column 4, lines 21-45). However, **Burton does not specifically disclose the suture as comprising a tube within the inner lumen.**

Davis et al. (hereinafter Davis) also discloses a braided wick for transmitting fluids (column 1, lines 14-22). The wick advantageously comprises a hollow inner braid within an outer braid where the inner braid comprises openings between the braided filaments (column 3, lines 26-28, 44-45, 68-74). This provides an efficient method of transporting the fluid along the length of the wick through capillary action (column 3, lines 25-45). Davis teaches the flow of fluids is not restricted in either an axial or radial direction when utilizing **a hollow inner tube** (column 3, lines 35-36). Therefore, in view of this advantage, it would have been obvious at the time of the invention for the suture/wick of Burton to comprise an inner tube within the inner lumen as disclosed by Davis.

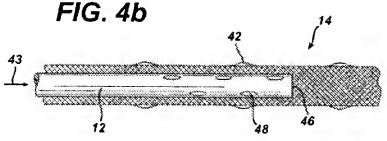
Although Davis does not specifically disclose the ratio of the outer diameter of the inner tube to the inner diameter of the tube, it would have been obvious to one of ordinary skill at the time of the invention for Davis to also comprise a tube diameter ratio of greater than 1.7, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (In re Alter, 105 USPQ 233 (CCPA 1955)).

> Applicant's arguments filed 04/29/2008 have been fully considered but they are not persuasive. Specifically, Applicant argues that Burton teaches the "wick" not a "braided suture" as a hollow monofilament. However, Burton teaches the wick is a suture (column 4, lines 21-31) and is braided (column 4, lines 32-33). Additionally, Burton specifically discloses the wick as a hollow monofilament (column 4, lines 46-49). Therefore, the wicks of Burton overlap the instantly claimed suture and clearly comprise braided, hollow monofilaments.

Burton, U.S. Patent No. 4,159,720, proposes a means for delivering a prescribed liquid medicine or other fluid to a subcutaneous tissue. The device includes a reservoir on the outside of the body for holding a supply of the prescribed liquid, the reservoir being adhesively attached to the skin near the tissue to be treated. The reservoir feeds the liquid to absorbent or capillary wicks adapted to pass through the skin to be installed in the subcutaneous tissue to which the fluid is to be fed. The wicks may be provided in several forms such as twisted or braided suture material, the ends of which, in some instances, may be encased in plastic or the wicks can be hollow monofilaments with lateral perforations. The wicks, in whatever form, are guided from the outside into their installed positions in the subcutaneous tissue with conventional cutting or tapered surgical needles, and in the modification making use of a plastic casing, a slightly modified needle is used to install the wick cover.

By contrast, the invention of independent claim 1, as shown in FIG. 4b below, includes in relevant part at least one passageway [12] coaxial with at least a portion of a braided suture [14], and having proximal and distal ends and a diameter that is less than a outer diameter of the braided suture and having one or more openings [48] therein so that the at least one passageway conducts fluid to the plurality of interstices of the braided suture and a distal end [46] of the at least one passageway is disposed between proximal and distal ends of the braided suture.

FIG. 4b



Similarly, the invention of independent claim 2, includes in relevant part a tube [12] coaxial with at least a portion of a braided suture [14], having an outer diameter that is less than an outer diameter of the braided suture and an inner diameter, and having one or more openings [48] therein so that the tube conducts fluid to the plurality of interstices of the braided suture and the ratio of the outer diameter of the tube to the inner diameter of the tube is greater than 1.7.

Advantageously, for active sutures that will be tied into surgically acceptable knots such as square knots or surgeons knots, preferably the ratio of the tube outside diameter (O.D.) to inside diameter (I.D.) is greater than 1.7, wherein experimental data indicates that extruded polymeric tubes produced from polypropylene, with outside diameters ranging from 0.005" to 0.010", with Youngs Moduli ranging between 0.1 and 3 GPa, with outside diameters (O.D.s) that are less than 1.7 times that of their inside diameters (I.D.s) will buckle and collapse when the braided sutures in which they are embedded are tied into square knots similar in form to those commonly used in surgical procedures (see, e.g., paragraphs [0038] and [0044] of the published application).

In addition, the inventions of independent claims 1 and 2 include the recognition of the problems of merely relying on capillary action as with the prior art device of Burton and advantageously provides a high level of drug delivery rate control and enables a physician to start or stop drug

administration at his/her discretion, as compared thereto (see, e.g., paragraphs [0007]-[0009] of the published application).

By contrast, as shown in FIGs. 6, 9 and 14, reproduced below, and discussion thereof, Burton merely discloses a wick 48 that can be a hollow monofilament 100 with lateral perforations 102 (see, e.g., col. 4, lines 46-49 of Burton) and with an enlarged end 56. Contrary to the assertion in the present office action, the noted features or advantages of at least independent claims 1-2 are not disclosed, taught or suggested by Burton.

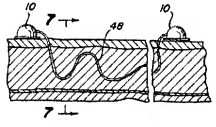


Fig.6

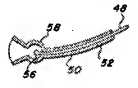


Fig. 9

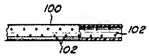


Fig. 14

Accordingly, Burton merely discloses that the "wick" 48 of Burton can be a hollow monofilament. As such, Burton proposes a braided suture, and a connector 58; **or, alternatively**, a hollow monofilament 100, and a connector 58. Nowhere does Burton describe the use of both the braided suture and the hollow monofilament **in the same assembly**. Accordingly, the present office action correctly admits that "Burton does not specifically disclose the suture as comprising a tube within the inner lumen." Moreover, the present office action incorrectly characterizes Burton as disclosing that suture material must be present at a distal end to take in fluid. Specifically, in Burton, the ends of the "hollow monofilament 100" can absorb a fluid by "capillary action," as

disclosed at col. 5, lines 6-8 of Burton, so that, contrary to the assertion in the present office action, suture material need not be present.

Davis et al. fails to cure the noted deficiencies in Burton, and as shown in FIG. 2 and discussion thereof, merely discloses a braided capillary device that includes an outer braid 2, braided around an inner braid 3, and with a small central passage way formed therein (see, e.g., col. 3, lines 26-56 of Davis et al). Accordingly, contrary to the assertion in the present office action, Davis does not disclose a hollow inner tube. Moreover, Davis et al. is silent with respect to the relationship or advantages of the ratio of the diameters of the outer braid 2 and the inner braid 3, and which according to the present invention is not a mere design choice, as asserted by the present office action, but rather provides the noted advantages of independent claim 2.

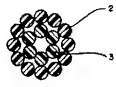


FIG. 2

Thus, the noted features or advantages of at least independent claims 1 and 2 are not disclosed, taught or suggested by Burton and Davis et al., alone or in combination. In addition, there would be no motivation to modify Burton and/or Davis et al. to arrive at the invention of independent claims 1 and 2, absent improper hindsight reconstruction of the invention, based on Applicant's invention disclosure.

As stated in MPEP §2131, in order to constitute anticipation under the law, a patent or publication must contain within its four corners a sufficient description to enable the person of ordinary skill to make the invention without undue experimentation. All material elements of a claim must be found in one

prior art source, a mere suggestion is not enough and essential elements are not to be read into a reference. Burton clearly fails to teach each and every element of applicant's invention, as presently claimed. Nowhere does Burton disclose an active suture that includes a tube having an internal passageway for conducting fluid to the plurality of interstices of the braided suture. Accordingly, it is respectfully requested that the Examiner's rejection of claims 1, 4 and 6 under 35 U.S.C. §102(b) as being anticipated by Burton be withdrawn.

It is respectfully submitted that, as the Federal Circuit noted in In re Gordon, at 221 USPQ 1127, 733 F.2d 902, "the mere fact that the reference could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification." It is respectfully submitted that the lack of technical motivation for making the modifications necessary to arrive at applicant's claimed invention is evidence that the suggestion for the modification could not have come from the reference itself. In view thereof and the arguments above, the applicant respectfully requests that the rejection of claim 2 under 35 U.S.C. 103(a) as being unpatentable over Burton and Davis et al., be removed.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 50-2478(14619).

It is respectfully submitted that the present claims are in condition for allowance. Prompt notification of allowance is respectfully solicited.

Respectfully submitted,

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